

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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**Food and Drug Administration**

**Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on July 29, 1999, 8 a.m. to 5 p.m.

*Location:* Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

*Contact Person:* Mary J. Cornelius, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2194, ext. 118, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12523. Please call the information Line for up-to-date information on this meeting.

*Agenda:* The committee will discuss, make recommendations, and vote on a premarket approval application for a urethral bulking and coaptation device for the treatment of stress urinary incontinence due to intrinsic sphincter insufficiency. The committee will also discuss possible revisions to the document entitled "Draft Guidance For Preparation of PMA Applications for Testicular Prostheses," issued March 16, 1993. Single copies of the draft guidance are available

to the public by calling 1-800-899-0381 or 301-827-0111, and requesting Facts-On-Demand document number 809, or on the Internet at “<http://www.fda.gov/cdrh/ode/oderp809.html>”.

*Procedure:* On July 29, 1999, from 8:30 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 23, 1999. Oral presentations from the public will be scheduled between approximately 9 a.m. and 9:30 a.m., and between approximately 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 23, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

*Closed Committee Deliberations:* On July 29, 1999, from 8 a.m. to 8:30 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding present and future FDA issues.

FDA regrets that it was unable to publish this notice 15 days prior to the July 29, 1999 Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: July 13, 1999  
July 13, 1999

Linda A. Suydam

Linda A. Suydam  
Senior Associate Commissioner

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